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Pressure indices in peripheral arterial disease assessed by infrared photosensors

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Pressure indices in peripheral arterial disease assessed by infrared photosensors

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Abstract

Ankle-brachial index (ABI) assessment by Doppler is operator-dependent and limited in calcified arteries. For the detection of peripheral arterial disease (PAD), we evaluated ABI and toe-finger (ToFi) pressures by infrared (IR) sensors at the digits and compared with standard Doppler (Doppler-ABI) in 100 PAD patients and in 15 controls. Pressure indices were obtained in 86% for Doppler-ABI, 82% for IR-ABI, and 94% for IR-ToFi ($p < 0.01$).

According to Bland Altman analysis, IR-ABI and Doppler-ABI are exchangeable (loa -0.30; 0.30, bias -0.003, 95%CI -0.02; 0.02) whereas IR-ToFi was not (loa -0.23; 0.61, bias of 0.2, 95%CI 0.16; 0.23). IR-ToFi revealed the best inter-and intra-rater agreement (0.92/0.98) followed by IR-ABI (0.74/0.98) and Doppler-ABI (0.66/0.89).

Ankle-brachial arterial pressure index can be assessed by infrared photosensors.

Although toe-finger index is not exchangeable with standard Doppler it will need further exploration to define its value for diagnosis PAD due to its excellent inter- and intra-rater agreement.

Key words: peripheral arterial disease, ankle-brachial index, Doppler, infrared sensors

Introduction

Peripheral arterial disease (PAD) affects about 20-25% of the population over 65 years of age and is responsible for about 64% of all lower limb amputations.¹ PAD is associated with impairment in functional activity and with an increased risk of cardiovascular events, a high risk for nonhealing wounds, infection, cardiovascular events, limb loss, higher rate of hip bone loss and fractures.¹⁻⁷ Therefore, different studies called for improved diagnosis and screening for PAD to allow earlier risk factor management for this high risk group.^{8,9}

The ankle-brachial index (ABI) calculated from systolic arterial pressures of the upper and lower extremities are a reliable method to detect PAD. It is widely applied in practice, using the Riva Rocci method for upper extremity and Doppler for lower extremity arterial pressure measurement.^{3, 8, 10} The Doppler signal is generally considered the most easily discernible method of assessing peripheral arterial flow and can be heard as an audible signal.¹¹ However, there are several sources of error with this method including attenuation of Doppler sound wave from the arterial wall and incompressibility of infrapopliteal arteries due calcification at the site of sampling.¹¹ Furthermore, obtaining ABI with Doppler may be cumbersome and compromised by difficulty in finding the suitable artery as a result of poor blood flow, extremity oedema, obesity or patient non-compliance.^{11, 12} Patient and investigator movement may cause technical difficulties in holding the probe stable. Advanced occlusive disease, to an extent that the systolic flow velocity is below 2-3 cm/sec, results in undetectable or weak signal by Doppler method.¹¹ Therefore, other non-invasive techniques such as infrared sensors, strain gauge instruments and radionuclide methods have been explored and shown to be reliable in the assessment of PAD.^{11, 13-16} However, the problem with assessment of incompressible arteries remains. In

contrast to tibial and peroneal arteries, digital arteries are usually free of arterial wall calcifications. We assumed that perfusion indices assessed by infrared (IR) sensor method at the ankle and the phalanges can be used instead of the Doppler technique to simplify measurement of pressure indices. For that purpose we performed arterial pressure indices assessment by IR sensor with compression of either the ankle or digits in comparison to the Doppler technique in patients with PAD and in healthy controls.

Study Design and Methods

Study Design

This study was designed as a non-invasive assessment of arterial blood pressures in subjects with and without PAD. The study was performed at the vascular laboratory of a tertiary referral hospital. Study subjects were either patients that were referred for vascular diagnosis due to clinical signs of PAD (Doppler ABI <0.9), or PAD patients that were followed after lower limb revascularization procedures (Table 1). In addition, healthy volunteers without any history or signs of vascular disease or cardiovascular risk factors were recruited (ABI > 1.0). Patients were included when ABI < 0.9 , or when ABI > 0.9 and known atherosclerotic disease of the lower extremity (duplex sonography, angiography or previous angioplasty). Exclusion criteria were tissue lesion that enabled cuff applications. The study was approved by the ethic committee (EK-1720/2009) and all subjects gave written informed consent.

Methods

All measurements were made in a warm, temperature controlled room (22°C), and 15 min were given for thermal acclimatization and resting. All measurements were performed in the supine position. Gold standard ABI (Doppler-ABI) was assessed as follows: The pressure indices were obtained by placing a 12/23-cm pneumatic cuff on the arm above the elbow level for brachial artery pressures using Riva Rocci method. For the ankle pressures the posterior tibial artery was taken, followed by the anterior tibial artery and the peroneal artery. The cuff positioned above the ankle was inflated until the waveform signal of the sampled artery disappeared. The cuff pressure then was slowly released until the Doppler probe first detected the arterial waveform. Doppler probes with frequencies of 8-MHz (Logidop 2, Kranzbühler, Solingen, Germany) were used. Systolic ankle pressures were divided by the higher of the 2 brachial artery pressures to calculate the Doppler-ABI.

The infrared pressures indices were obtained afterwards by infrared photosensors (Infraton 2000, Boucke u. Co., Reutlingen, Germany) fixed on the pulp of the thumb for upper extremity pressures and on the first toe or, if not available, on the second toe. For the ankle pressures (IR-ABI), cuffs were placed in identical manner as for the Doppler-ABI. The systolic pressures were recorded during release of the cuff pressure and systolic pressure was set at the return of flow wave on the infrared electronic tracings. Finger and toe pressures (IR-ToFi) were obtained by using a small 2x4 cm cuff (True-cuff, Neonatal 2, Fritac AG, 8005 Zürich) for digital pressure measurements. Inter- and intra-rater agreement of the Doppler-ABI and IR-ABI was calculated by pressure measurements of the brachial artery, digital artery of the thumb, anterior tibial artery and the digital artery of the first toe in 20 limbs by 2 different, blinded examiners.

Statistical analysis

All values are presented as median and interquartile range (IQR). IR-ToFi and IR-ABI were compared vs Doppler-ABI. Methods of measurements and data were compared following Bland and Altman.¹⁷ In particular, the differences between the IR assessments and Doppler-ABI were assessed by calculating the difference between the mean values (bias, including 95% confidence intervals) and computing the 95% limits of agreement. In addition, to assess validity of limits of agreement and explore potential data transformations, Bland-Altman plots were generated. A two sided p-value ≤ 0.05 was considered significant and all confidence intervals were computed at a confidence level of 95%. To allow for a replacement of one method with the other, differences within ranges of ± 0.3 for quotients and ± 20 mmHg for pressure measurements would be acceptable. Reliability was assessed via the computation of the intraclass correlation coefficient (ICC), based on a 2-way random fixed effects model. R software (R Development Core Team 2011, R Foundation for Statistical Computing, Vienna, Austria) was used for these statistical analyses. Differences in the number of measurable patients by IR-ToFi, IR-ABI and Doppler-ABI (differences in nominal variables) were assessed by Fisher's exact test using StatView 5.0.1. (Adept Scientific, Acton, Mass.).

Results

Infrared vs Doppler technique

The characteristics of patients (n = 100, 187 limbs) and controls (n = 15, 30 limbs) are shown in Table 1, and absolute pressures and pressure indices in Table 2. Pressure indices were assessable in 86% with Doppler-ABI, in 81% with IR-ABI and in 94% with IR-ToFi. There were significant differences in the number of measurable

patients between the methods: Doppler-ABI versus IR-ToFi ($p = 0.0091$), Doppler-ABI vs IR-ABI ($p < 0.0001$) and IR-ABI vs IR-ToFi ($p < 0.0001$).

In 11% of limbs Doppler-ABI and IR-ABI could not be assessed because of incompressibility. In 1.7% no pressure indices (Doppler-ABI, IR-ABI, IR-ToFi) were assessable because of leg amputations and in 0.9% no IR pressures were obtained because of toe amputations. In 1.3% of the limbs, ankle cuff compression (Doppler-ABI, IR-ABI) was not obtained because of pain. No pulse wave forms at the pulp of toe were recorded in 3.9%.

Doppler-ABI and IR-ABI comparison by Bland-Altman resulted in a minimal bias of -0.003 (95% CI bias [-0.02, 0.02]) (Figure 1). Median Doppler-ABI (IQR) were 1.00 (0.36) vs 0.94 (0.33) for IR-ABI. IR-ToFi however differed from Doppler-ABI with a bias of 0.2 (95% CI bias [0.16, 0.23]) as shown in Figure 2. Median IR-ToFi (IQR) was 0.72 (0.38) (Table 3).

Inter- and intra-rater agreement of the Doppler and IR technique

Inter- and intra-rater agreements are shown in Table 4. Absolute agreement of the Doppler-ABI is 0.66 between different raters and 0.89 within the same rater; for IR-ABI 0.74 and 0.98 and of infrared ToFi 0.92 and 0.98. A value above 0.7 is typically designated good agreement.

Discussion

This study shows that peripheral arterial perfusion can be assessed by IR sensors with either ankle or digital artery compression with a substantially lower inter- and intra-rater variability compared to the standard Doppler measurements, indicating that IR assessment is less operator-dependent. Following Bland and Altman for the comparisons of the different methods (IR vs Doppler), we could demonstrate that the assessment of ABI by IR and ankle compression can be used as an alternative. Surprisingly, digital compression and IR measurement did not result in an exchangeable index for Doppler-ABI. The finding that IR-ToFi is not an alternative index for Doppler-ABI was unexpected, since a tibial-brachial pressure ratio in controls is >1.0 and toe-brachial pressure ratio >0.7 . Likewise, a toe-to-finger digital artery pressure ratio would be 1.0. Due to the different vessel wall composition between brachial and tibial artery, with the tibial arteries containing a thicker muscular layer, the applied cuff pressure to reach systolic pressure at the ankle usually exceeds the brachial pressure slightly resulting in a Doppler-ABI of above 1.0 in healthy conditions. This could explain the different values of IR-ToFi to Doppler-ABI in controls (1.00 vs 1.06). However, there was substantial difference in PAD patients between IR-ToFi (0.64) and Doppler-ABI (0.89). Statistical evaluation according to Bland and Altman did hence not result in exchangeable pressure indices for digital vs ankle/brachial cuff compression. Nevertheless, the greater difference between healthy controls and PAD patients for IR-ToFi ($\Delta = 0.34$) than for Doppler ABI ($\Delta = 0.06$) could indicate that IR-ToFi, although not tested in this study, could be a more sensitive marker for peripheral perfusion impairment. This will need further evaluation because of the higher inter- and intra- rater agreement and greater number of limbs that could be assessed. This is certainly an advantage of digital arterial compression, since digital arterial segments are usually free of medial calcinosis. In patients with elevated ABI (>1.3) caused by calcification of the

arteries, as is often the case in diabetes or renal failure patients, toe-brachial index has been used because digital arteries are usually unaffected by calcification.^{1, 18, 19} Toe brachial index though, is lower than normal ABI, as the blood pressure in the toe generally is lower than the one in the ankle. A disadvantage of IR assessment is that toe pressure evaluation does not differentiate between occlusive disease of the different arteries and thus for the localisation of the occlusion other techniques are necessary.^{11, 20} In addition, the lower rate of ABI assessment by IR-ABI compared to Doppler-ABI requires further improvement and standards, i.e. sublingual nitro glycerine application to assure patent digital arteries. However, PAD is still underdiagnosed and often not diagnosed by a vascular testing in a general practitioner setting due to the lack of an easy, reproducible and cheap device. Therefore, improvements in current and alternative techniques are warranted and appropriate statistical testing needed. To our knowledge, this is the first study to evaluate IR and Doppler pressure assessment following statistical evaluations according to Bland and Altman, which is considered to be the appropriate testing for the comparison for exchangeability of different methods. The Czech-post MONICA study, reports high negative predictive value allows using it as a screening tool for PAD for an oscillometric device (BOSO ABI device, Bosch GmbH, Jungingen, Germany for PAD screening.²¹ Furthermore, Sadiq and Chithriki reported a good correlation between Doppler-ABI and IR-ABI using a simple linear regression.¹¹ Although this is not the appropriate statistical test, their data and our study support the use of IR-ABI as an easier and more reliable assessment for PAD at least as a screening test. Another proposed technique for perfusion evaluation is Laser Doppler that could be used as the IR photosensor for ankle-brachial pressure assessments. A recent study reported ABI assessment by laser Doppler. Although Ludyga et al. found that ABI-laser Doppler measurements are easy, quick and in correlation, their study

lacks a substantial number of evaluated patients (only 22 patients) and the appropriate statistical testing according to Bland and Altman.²²

In conclusion, ankle-brachial pressure assessment by infrared photosensor is an easy and reliable screening test for PAD when used with standard cuff compression. Although toe-finger-pressure assessment is not exchangeable with Doppler-ABI, further research is warranted, since that index allows an arterial perfusion evaluation for lower limb with mediacalcinosis and shows an excellent intra- and interrater variability..

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Conflicts of interest

No author has any conflict of interest in relation to this study.

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